

WHAT IS CLAIMED IS:

1. A respirable particle-based pharmaceutical formulation for delivering a medicament via insufflation, comprising controlled release particles of a cohesive composite of a medicament and a pharmaceutically-acceptable carrier comprising a polysaccharide gum of natural origin, wherein the average particle size of the said cohesive composite particles is from about 0.1 to about 355 microns in diameter.

2. The formulation of claim 1, wherein the average particle size of said cohesive composite particle is from about 0.1 to about 10 microns.

3. The formulation of claim 1, wherein the average particle size of said cohesive composite particle is from about 1.0 to about 355 microns.

4. The formulation of claim 3, wherein the average particle size of said cohesive composite particle is from about 10 to about 125 microns.

5. The formulation of claim 1, wherein said polysaccharide gum comprises a heteropolysaccharide gum.

6. The formulation of claim 1, wherein said polysaccharide gum comprises a homopolysaccharide gum.

7. The formulation of claim 1, wherein said polysaccharide gum comprises a starch.

8. The formulation of claim 5, wherein said heteropolysaccharide gum is xanthan gum.

9. The formulation of claim 5, wherein said heteropolysaccharide gum is locust bean gum.

5 10. The formulation of claim 1, wherein said polysaccharide gum comprises a heteropolysaccharide gum and a homopolysaccharide gum in a ratio of from about 1:3 to about 3:1.

10 11. The formulation of claim 1, wherein the drug to gum ratio is from about 0.5:100 to about 1:1.

15 12. The formulation of claim 11, wherein the drug to gum ratio is from about 1:100 to about 1:2.

20 13. The formulation of claim 1, further comprising from about 0.1 to about 50% by weight of a cationic cross-linking agent comprising an alkaline metal or an alkaline earth metal sulfate, chloride, borate, bromide, citrate, acetate or lactate.

25 14. The formulation of claim 13, wherein said cationic cross-linking agent is present in an amount of from about 1 to about 10% by weight.

30 15. The formulation of claim 13, wherein said cationic cross-linking agent is selected from the group consisting of potassium chloride and sodium chloride.

35 16. The formulation of claim 1, wherein said pharmaceutically acceptable carrier further comprises an inert saccharide diluent selected from the group consisting of monosaccharides, disaccharides and mixtures thereof.

17. The formulation of claim 16, wherein said inert saccharide diluent is selected from the group consisting of dextrose, sucrose, galactose, lactose and mixtures thereof.

5           18. The formulation of claim 1, wherein said pharmaceuticaly acceptable carrier further comprises a pharmaceutically-acceptable surfactant in an amount of from about 0.5 to about 3% by weight of the controlled release carrier.

10           19. The formulation of claim 18, wherein said surfactant is selected from the group consisting of pharmaceutically-acceptable anionic surfactants, cationic surfactants, amphoteric (amphipathic/amphophilic) surfactants, non-ionic surfactants, and mixtures thereof.

15           20. The formulation of claim 1, wherein said controlled release particles are compressed together to form a solid mass.

20           21. A method of preparing a controlled release pharmaceutical formulation for insufflation therapy, comprising

25           coprocessing a mixture of a medicament together with a polysaccharide gum of natural origin to form a cohesive composite of medicament and gum and thereafter milling said cohesive composite of medicament and gum to obtain particles having a diameter from about 0.1 to about 355 microns.

30           22. The method of 21, further comprising milling said polysaccharide gum prior to coprocessing said gum with said medicament.

35           23. A method of treating a patient via oral or nasal insufflation therapy, comprising

36           coprocessing a mixture of a medicament together with a polysaccharide gum of natural origin to form a cohesive composite of medicament and gum and thereafter milling said resultant cohesive composite of medicament and gum to obtain particles having a diameter from about 0.1 to

about 355 microns,

incorporating the resultant particles into a suitable inhalation device; and

5 administering a metered unit dose of the cohesive composite to a patient with said inhalation device to provide a therapeutically effective dose of medicament for absorption in the respiratory tract or intra-nasally.

10 24. A capsule, cartridge blister or aerosol container containing a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising a polysaccharide of natural origin, wherein the average particle size is from about 0.1 to about 355 microns in diameter.

15 25. A method for providing an oral insufflation formulation for controlled release of a medicament in the upper airways of the respiratory tract, comprising

20 granulating a mixture of a medicament together with a polysaccharide gum of natural origin, drying the resultant granulation,

25 milling the resultant cohesive composite of medicament and gum to obtain particles having a diameter from about 0.1 to about 355 microns, and

incorporating the resultant particles into an inhalation device suitable for delivering a unit dose of said particles to the upper respiratory tract of a human patient.

add A2

add B1